IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

IMMOGENE EMODY,

Plaintiff,

v.

MEDTRONIC, INC., et al.,

Defendants.

CIVIL ACTION NO.

02-AR-0111-S

MEMORANDUM OPINION

Before the court is a motion for summary judgment filed by defendants, Medtronic, Inc. and Medtronic Sofamor Danek USA, Inc. (collectively "MSD").[1] Immogene Emody ("Emody") filed this action under Alabama Extended Liability Manufacturer's Doctrine (AEMLD). MSD's motion is due to be granted.

Statement of Undisputed Facts

Emody first saw a Dr. Stan Faulkner on October 4, 1996, for chronic back pain despite four prior back operations. Emody suffered from "spinal stenosis" and "degenerative scoliosis." Dr. Faulkner, an orthopedic surgeon, recommended "posterior lumbar

[1] According to the defendants Medtronic Sofamor Danek USA, Inc. manufactured and distributed the "TSRH Spinal System" implanted during plaintiff's operation. Medtronic, Inc. is a remote parent company with nothing to do with this case. As a result, the balance of the motion refers only to Medtronic Sofarmor Danek USA, Inc. However, summary judgment is sought with respect to both defendants on the same grounds.

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interbody fusion" across five levels of Emody's spine. Before Emody's surgery, Dr. Faulkner knew of the risks of instrumented spinal fusion surgery, including the possibility that the instrumentation may break, cause additional pain, or result in the need for additional surgery. With experience in over 1,000 prior spinal fusion surgeries, Dr. Faulkner had made independent assessments of how the TSRH system performed. Dr. Faulkner testified that he did not obtain his information about the risks and benefits of the TSRH instrumentation from MSD. The source of his knowledge came from medical books, journals, newsletters, meetings, and peer discussions. He did not rely on information from MSD. He did not even read the package insert provided by MSD.

The TSRH Spinal System is a multi-component medical device consisting of rods, cross-links, hooks, and screws. For each patient the surgeon selects the size and configuration of the component parts. The package insert provided by MSD with the TSRH instrumentation discusses the need for a second operation to remove the instrumentation. Concerning marring breakage, renewed pain, and falls, the insert states that potential adverse events include but is not limited to: breakage of any or all of the components, development of pain, and device component fracture. The insert recommends that the patient be warned to avoid falls. The insert also states that the system is intended only to

provide stabilization during the development of a solid fusion and should be removed after the development of a solid fusion. The insert notes that additional surgery may be necessary to correct some of these anticipated adverse reactions.

On November 13, 1996, Dr. Faulkner performed the spinal fusion with MSD's titanium TSRH instrumentation. Spinal instrumentation serves as "an internal support and a brace." Dr. Faulkner testified that the device holds the spine together in the position it needs to be in while it is fusing. Dr. Faulkner uses spinal instrumentation in 98% of the spinal fusion surgeries he performs. From the various TSRH components, Dr. Faulkner constructed a custom made implant for Emody. Dr. Faulkner's assistant explained to Emody the potential complications of the surgery. Emody contends that she was told the rods would last forever in her back and not need to be taken out. Dr. Faulkner admits that Emody was told that the plan was to leave the rods in place forever but that Dr. Faulkner does remove the instrumentation in about 20% of his patients and that Emody was told that the instrumentation may get loose or break or cause pain and may have to be removed later.

After surgery, Emody saw Dr. Faulkner for several routine follow-up visits until August 20, 1997. On August 20, 1997, although the fusion was progressing well, Emody's spine was not totally fused. Dr. Faulkner scheduled Emody for another

appointment in a year. Emody did not keep that appointment and did not see Dr. Faulkner at all for the next three years. Whether this constituted contributory negligence as a matter of law is a matter of legitimate dispute. On October 11, 2000, Emody returned to Dr. Faulkner complaining of increased back pain. X-ray's showed a non-displaced broken rod on the right side and a solid appearing spinal fusion. Dr. Faulkner had never seen before a broken rod with a solid fusion. It was his opinion that the rod broke before the spine was totally fused due to trauma. Emody admitted that she had fallen down three to four times since her surgery in 1996.

Dr. Faulkner gave Emody the option of leaving the rod in or having it surgically removed. It was his opinion that the pain was caused by the hardware and not because of the fracture of the rod. Dr. Faulkner testified that in 20% of his patients he removes the rod for that specific reason. On January 9, 2001 Emody opted to have the rod removed. Emody claims that she has suffered immensely from physical pain and mental pain because the broken TSRH titanium rods were removed.

Emody stated that her medical experts are: (1) Dr. Faulkner, with his deposition serving as an expert report, (2) a psychiatrist, Dr. Margaret Sellers-Bok, M.D., ("Dr. Sellers-Bok") and (3) Raymond Thompson, Ph.D. ("Dr. Thompson"), a professional engineer. Dr. Faulkner testified that the TSRH rod did not have

any defects in either its design or manufacture. Dr. Faulkner also opined that no defect caused the rod to break and that no defect caused any injury to Emody.

Dr. Sellers-Bok is a psychiatrist who has been treating Emody for depression, anxiety, and psychotic symptoms since June of 1999. Dr. Sellers-Bok's notes do not mention Emody being in pain of any sort until October of 1999 and do not mention her back until July of 2001. Dr. Sellers-Bok's notes seem to indicate that one source of Emody's depression was her hypothyroidism. Dr. Sellers-Bok's records do not contain any medical causation opinions concerning the rod.

Dr. Thompson subjected the removed rod to objective metallurgical testing for composition, hardness, and microstructure. Dr. Thompson's test indicate that the rod met ASTM (American Society for Testing and Materials) standards for chemistry, for hardness, and for microstructure. Based on subjective visual inspection, it is his opinion that the rod was "substandard in respect to surface finish leading to multiple cracking, failure, and reduced service life." However, his report does not reveal the standard against which he declared the rod to be substandard. He described seeing several scratches and impressions. When he examined the rod it had been out of MSD's hands for about six years. Dr. Faulkner also testified that before implantation he cut and shaped the rod to match Emody's

anatomy. The rod then spent four years in Emody's body. When it first broke is anybody's guess. After the break was discovered, the rod and other components were removed by a process that broke the heads off of several the screws. Dr. Thompson never states that any of the alleged defects was the medical cause of injury, and as a non-physician he would hardly have expressed such an opinion even if he had formed it.

Analysis

MSD argues that it is entitled to summary judgment because Emody has not offered any expert testimony to establish medical causation. An essential element of all product liability cases is expert testimony, passing *Daubert* muster, that a defect was the medical cause of plaintiff's claimed injuries. *Tidwell v. Upjohn Co.*, 626 So.2d 1297, 1299 (Ala. 1993). Has Emody produced admissible evidence that a defect in the rod caused it to break and that the broken rod caused her injuries? The answer is "No." Emody offers the expert report of Dr. Thompson, the deposition of Dr. Faulkner and the records of Dr. Sellers-Bok. None of these witnesses offer any opinion that a defect in the rod caused injury to Emody. Dr. Thompson, an engineer, states that the substandard surface finish led to multiple cracking, failure, and reduced service life. However, Emody's medical expert, Dr. Faulkner, states that the rod had been in Emody's back for four years and had been subjected to numerous falls. Furthermore, the

rod had been cut and shaped to fit Emody's anatomy. It was not in its original manufactured condition when implanted.

Neither one of Emody's treating physicians opines that the broken rod caused Emody injury. A psychiatrist would not be qualified to state any such opinion any more than Dr. Thompson would. Dr. Faulkner's testimony does not support any of Emody's contentions. Dr. Faulkner testifies that the rod was not defective, that he was adequately warned, that no defect caused the rod to break, and that no defect caused injury to Emody. Dr. Faulkner testifies that he removed the rod because the "bulk and size of the thing . . . if any, was causing the pain from her instrumentation. I don't think it was the break", and that she was having pain from the hardware which he sees in 20% of his patients.

The medical records Emody offers from her psychiatrist are not helpful. These records do not mention the TSRH rod, its condition, or how that condition had anything to do with Emody's complaints. Proximate causation is an essential element of Emody's claim. As stated, psychiatrist do not qualify as experts on orthopedic devices or surgery.

Because Emody has failed to raise a genuine dispute of material fact as to the element of causation, not even responding to defendants' argument, MSD is entitled to summary judgment.

If this did not end the matter, MSD also argues that the

undisputed facts show that Emody cannot prove any defect in MSD's TSRH rod. As discussed above, Emody has not offered proof of a manufacturing defect. Emody claims she can prove a manufacturing defect through the expert testimony of Dr. Thompson. The court disagrees. Dr. Thompson criticizes the surface of the rod but admits that the rod passed every objective test he performed. Further, his opinion lacks any objective or peer reviewed basis. His report reveals no methodology beyond merely looking at the rod and claiming to see "residual grinding marks." But Dr. Faulkner bent the rod to shape it to fit into Emody's back. The rod was then exposed to the stress of supporting Emody's back and exposed to direct trauma from Emody's numerous falls. It was left in Emody's back for 4 years. The rod was also broken into several parts when it was removed from Emody's back. Dr. Thompson did not offer an alternative design or even test an alternative design. He did not contact Dr. Faulkner or any other physician that treated Emody. He did not cite any scientific literature to support his theory and he ignored the numerous ways the rod's finished could have been marred. Dr. Thompson's opinion concerning "grinding marks" is based solely on visual inspection. He provides no factual basis for concluding that the scratches, impressions, and other imperfections he saw in 2002 existed when MSD sold the rod in 1996. Dr. Thompson's opinion, if even admissible, does not raise a genuine dispute of material fact

rendering summary judgment appropriate against Emody's manufacturing defect claim.

According to MSD, under AEMLD, prescription medical devices are unavoidably unsafe products, and where inherent risks are at issue, the only other permissible theory of liability is inadequate warning. Emody claims that the application of the unavoidably unsafe products doctrine should not apply to an implantable, prescription-only medical device. The court agrees with MSD. The TSRH spinal rod is a prescription-only medical device that has an unavoidably unsafe characteristic. *See Stone v. Smith, Kline, & French Laboratories*, 447 So. 2d 1301 (Ala. 1984); *Purvis v. PPG Industries, Inc.*, 502 So.2d 714, 718 (Ala. 1987). Emody next claims that an allegation of improper manufacture defeats the unavoidably unsafe product doctrine. However, as established above, Emody has no expert evidence to support a claim of manufacturing defect.

Emody's warning-related complaint appears to be that Dr. Faulkner told her that the rod would last "forever" if her fusion was successful. Under the learned intermediary rule, the manufacturer's duty to warn is limited to an obligation to advise the prescribing physician of any potential dangers. *Stone*, 447 So.2d at 1304. MSD demonstrated that the package insert contained adequate warnings concerning the risk of breakage. Furthermore, Dr. Faulkner chose not to follow MSD's removal warning because

based on his experience he considered removal unnecessary in 80% of his patients. He testified that he did not rely on MSD's warnings. Emody has failed to present a genuine dispute of material fact concerning MSD's warnings.

MSD is also entitled to summary judgment on Emody's implied warranty claims because such claims are subsumed by AEMLD and thus fail for the same reasons that Emody's AEMLD claim fails. *Shell v. Union Oil Co.*, 489 So.2d 569, 571 (Ala. 1986), *Brock v. Baxter Healthcare Corp.*, 96 F. Supp.2d 1352, 1356 n.2 (Ala. 2000). Her express warranty claim nowhere specifies what the purported express warranty was. In her affidavit, Emody does not claim that MSD told her anything, and she admits that Dr. Faulkner, not MSD, told her the rods would last forever. If she relied on any representations they were made by Dr. Faulkner and not by MSD. MSD is entitled to summary judgment against Emody's warranty claims.

Conclusion

This court, by separate order, will grant MSD's motion for summary judgment in its entirety.

DONE this 7th day of January, 2003.

WILLIAM M. ACKER, Jr.
UNITED STATES DISTRICT JUDGE